#### REMARKS

### **Status of Case**

Claims 1-6, 26-29, 32-36, 38, 56, 58-66, 68-76, 78-86 and 88-95 are currently pending in the application. Claims 7-25, 40-55 and 96-102 previously were withdrawn. Claims 30, 31, 37, 39, 57, 67, 77 and 87 previously were cancelled.

In the Office Action dated June 17, 2004, claims 1-6, 26-29, 32-36, 38, 56, 58-66, 68-76 78-86 and 88-95 were rejected.

In this Paper the Applicant: cancels claims 1-6 and 56 – 65 and presents arguments that claims 26-29, 32-36, 38, 66, 68-76, 78-86 and 88-95 are allowable over the cited art.

# **Arguments**

Claims 26-29, 32-36, 38, 68-76 78-86 and 88-95 were rejected under 35 U.S.C. 103(a) as being unpatentable over Ricciardi et in view of Furcht et al in view of North view Biosciences Inc. The Examiner cited U.S. Patent No. 6,303,288 to Furcht et al. as teaching:

"a sample collection pad that is placed on a plastic support, reference number 31, (see column 8, lines 41-44), where the figure shows a front surface that is available for the collection of material containing DNA and a rear surface that is *covered by plastic and is not available for DNA collection* (see figure 3)." (emphasis added).

The applicant respectfully disagrees. The specification of Furcht does not teach or suggest that the collection pad (32) of Furcht is <u>covered</u> by flexible plastic strip (31). Furcht mere says that pad 32 and strip 31 are <u>affixed</u>. Furcht states at Column 8, Lines 41-47:

"The genestrip 11 is comprised of a flexible plastic support strip 31 onto which is affixed the sample collection pad 32 and the reaction cocktail pouch 33 with attached cocktail fluid tube 35, depicted in phantom in FIG. 3 underlying a portion of the collection pad 32 and fluidly coupling the cocktail pouch 33 and the collection pad 32.

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Furcht further states at Columns 8-9, Lines 64-3:

On one end of strip 31 is affixed the FTA-treated collection pad 32 for DNA specimen collection. Proximal to the collection pad 32 is the reaction cocktail pouch 33, consisting of a sealed plastic reservoir (bag) containing the compilation of buffers, oligonucleotide primers and reaction additives used in the amplification reaction.

The Furcht specification only states that "on one end of strip 31 is affixed the FTA treated collection pad 32" and that genestrip 11 "is comprised of a flexible plastic support strip 31 onto which is affixed the sample collection pad 32" (See, above citations to Furcht). There is no statement in Furcht that the strip covers one side of the collection pad.

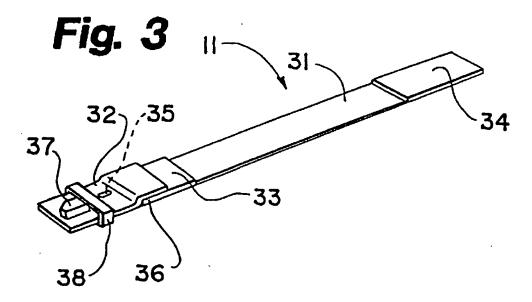


Figure 3 of U.S. Patent No. 6,303,288 to Furcht et al.

Figure 3 of Furcht does not support that a portion of strip 31 covers all of one side of the Furcht pad 32. Close examination of Figures 1 and 3 of the Furcht '288 patent shows that plastic support strip 31 terminates adjacent or under cocktail pouch 33, and that only a portion of collection pad 32 is mounted onto cocktail pouch 33 and none of pad 32 is attached to strip 31. In fact in Fig. 3 strip 31 appears to terminate at or under pouch 33.

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The Furcht specification calls for pad 32 to be mounted onto cocktail pouch 33 as is shown in Figs. 1 & 3, however, the specification makes no statement that the strip continues fully under pad 32 and Figs. 1 & 3 do not support such a construction. The Applicant has searched and can find no teaching within the text of the Furcht '288 patent which advocates any purpose for the Furcht plastic support strip 31 being a backing strip along the entirety of collection pad 32.

By contrast independent claims 26, 36, 38, 66, 76 and 86 of the present application each contain a structural limitation of "a covering" or "a protective layer" which prevents DNA contamination of a backside or a second side of the collection pad. The device of Furcht '288 does not have this limitation and cannot perform this function of preventing DNA collection on the backside of the absorbent pad.

Each of independent claims 26, 36, 38, 66, 76 and 86 contain a structural limitation for protecting one side of the collection pad:

### Claim 26:

".... said collection portion having a front surface and a rear surface, said rear surface having *a covering* thereon to prevent collection of material containing DNA.... "(emphasis added).

## Claim 36:

"....a collection portion, said collection portion having a front surface and a rear surface, said rear surface having *a covering* thereon to prevent collection of material containing DNA from the tongue and ... "(emphasis added).

## Claim 38

"... a collection portion, said collection portion having a front surface and a rear surface, said rear surface having a covering thereon to prevent collection of material containing DNA from mouth tissue adjacent to the tongue...." (emphasis added).

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## Claim 66:

"...a sample collection substrate for collection of DNA ... said substrate having a protective layer on said first side to limit contamination of said first side, said substrate having a second protective layer attached to a portion of said second side said second protective layer being foldable over said second side to prevent contamination of said second side . . ." (emphasis added).

### Claim 76

"... a sample collection substrate for collection of DNA... said substrate having a protective layer on said first side to prevent contamination of said first side, a second protective layer for covering said substrate second side, said second protective layer connecting with said first protective layer to form a protective pouch for holding said substrate prior to use . . . "(emphasis added).

### Claim 86

"...a sample collection substrate for collection of DNA...said substrate having a protective layer on said first side to limit contamination of said first side, a second protective layer for covering said substrate second side, said second protective layer connecting with said first protective layer to form a protective pouch for holding said substrate prior to use .... "(emphasis added).

As specifically stated in the specification of the present invention at page 13, lines 5-19, it is important to protect the reverse side of the collection pad to prevent DNA contamination derived from the individual collecting the specimen contacting the collection pad, and thus, contaminating the sample which is intended to be collected upon the collection pad. The Furcht specification does not suggest or teach any such protection for the collection pad and the Furcht Figures do not show such a covering or protective layer on the Furcht collection pad.

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# Conclusion

In view of the above arguments, the Applicant respectfully suggests that the rejection of claims 26-29, 32-36, 38, 66, 68-76, 78-86 and 88-95 is traversed and that the rejection be withdrawn. The Applicant further requests that independent claims 26, 36, 38, 66, 76 and 86 be allowed and that claims 27-29, 32-35, 68-75, 78-85 and 88 - 95 which depend from independent claims 26, 36, 38, 66, 76 and 86 also be allowed.

Reconsideration of the application as amended respectfully is requested. The foregoing amendment and remarks are believed to be responsive to every matter raised in the office action. However, if some matter has been overlooked, an opportunity to correct the oversight would be appreciated.

Respectfully submitted,

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